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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,790	01/30/2001	Endre Markovits Schersl	HAR-104	2203

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David I. ROCHE  
BAKER & MCKENZIE  
130 E. Randolph Drive  
Chicago, IL 60601

EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/772,790

Applicant(s)

SCHERSL, ENDRE MARKOVITS

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

### **DETAILED ACTION**

This application claims priority to Chile 209-2000. It is noted that the certified copy of the priority documents have not been received.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 drawn to a composition for lowering LDL-cholesterol levels or for elevating HDL-cholesterol levels in blood of a mammal comprising an ester of a policosanols or a mixture or esters of policosanols, classified in class 514, subclass 721, 723, and 724 for example.
- II. Claims 6-11 drawn to a method for lowering LDL-cholesterol levels or for elevating HDL-cholesterol levels in blood of a mammal comprising an ester of a policosanols or a mixture or esters of policosanols, classified in class 514, subclass 721, 723, and 724 for example.
- III. Claims 12-16 drawn to a composition for lowering LDL-cholesterol levels and triglycerides or for elevating HDL-cholesterol levels in blood of a mammal comprising an ester of a phytosterol or a mixture or esters of phytosterol, classified in class 514, subclass 169 for example.
- IV. Claims 17-22 drawn to a method for lowering LDL-cholesterol levels and triglycerides or for elevating HDL-cholesterol levels in blood of a mammal comprising an ester of a phytosterol or a mixture or esters of phytosterol, classified in class 514, subclass 169 for example.

- V Claims 23-28 drawn to a composition for lowering LDL-cholesterol levels and triglycerides or for elevating HDL-cholesterol levels in blood of a mammal comprising an ester of a policosanol or a mixture or esters of policosanols and an ester of a phytosterol or a mixture or esters of phytosterol, classified in class 514, subclass 721, 723, 724, and 169 for example.
- VI Claims 29-35 drawn to a method for lowering LDL-cholesterol levels and triglycerides or for elevating HDL-cholesterol levels in blood of a mammal comprising an ester of a policosanol or a mixture or esters of policosanols and an ester of a phytosterol or a mixture or esters of phytosterol, classified in class 514, subclass 721, 723, 724, and 169 for example.

Inventions Group I and II; Groups III and IV; Groups V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, for example, a statin (e.g., simvastatin) may be used in a method for lowering LDL-cholesterol levels and triglycerides or for elevating HDL-cholesterol levels in blood of a mammal.

Inventions for example Group I, II, and V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects

(MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are separate and distinct each from the other because they have different modes of operation and different effects.

The search for all inventions would place an undue burden on the Office in view of the diversity of the medical disorders to be treated and the corresponding diversity in the field of search for each.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### ***Election of Species***

This application contains claims directed to the following patentably distinct species of the claimed invention: policosanols or esters of policosanols; and/or phytosterols or esters of phytosterols.

Applicant is required under 35 U.S.C. 121 to elect a composition comprising a specified combination of individual active compounds for the elected group (see above restriction) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-35 are generic to a plurality of disclosed patentably distinct species. The claims read on the employment of various compounds e.g., policosanols or esters of policosanols; and/or phytosterols or esters of phytosterols, with great diversity of chemical structure, the search for all of which presents an undue burden on the Office. It is noted that a reference to one

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combination of individual agents would not be a reference to another combination of individual agents under 35 U.S.C.103.

A "specie" is a specific compound or treatment, with all parameters and/or substituent variables FULLY accounted for.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

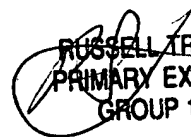
Because the above restriction/election requirement is complex, a telephone call to applicant's agent to request an oral election was not made. See M.P.E.P Sec. 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
July 8, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200